REMARKS

Reconsideration of the rejections set forth in the Office Action dated December 4, 2006 is respectfully requested. Claims 1-6, 14, and 15 are pending for examination and claims 7-13 stand withdrawn.

I. Amendments

The application has been amended to remove a claim to the benefit of co-pending U.S. Application No. 09/910,406, filed July 19, 2001; to U.S. Provisional Application No. 60/219,128, filed July 19, 2000; and to Japanese Application No. 317160 filed October 17, 2000. Removal of the priority claims brings the Applicant in compliance with 37 C.F.R. § 1.63(c).

Typographical errors in paragraph [0084] are corrected.

II. Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 2, 4-6, 14, and 15 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the specification. Applicants respectfully traverse the rejection.

The Examiner asserts that because of the range of activities of the various isoforms of interferon-tau (as taught by Alexenko et al., *J. Interferon Cytokine Res.* 19:1335-41 (1999)), a skilled artisan would not be able to predict *a priori* at which level a particular interferon-tau would be able to induce an increase in IL-10 while not affecting interferon-gamma blood levels nor inducing intolerable side effects.

Applicants direct the Examiner to the fact that pending claim 1 recites that a dose of an interferon-tau of greater than about 5×10^8 *Units* is given to produce the increase in blood IL-10 (emphasis added). The recited dose is given in antiviral Units, rather than, for example milligrams, to address the point raised by the Examiner. Specifically, Applicants establish in the specification that a dose of 5×10^8 Units of an interferon-tau with a specific activity of about 1×10^8 antiviral Units/mg protein (page 37, paragraph [0139]) achieves the desired therapeutic effect. Similarly, the antiviral activity for any isoform of interferon-tau can be ascertained using standard *in vitro*

cytopathic assays for interferons (see page 37, paragraph [0139] of the specification). After measuring the antiviral activity, the amount of protein required to achieve 5×10^8 Units can be calculated and administered. Therefore, a skilled artisan can very easily determine *a priori* the level of any particular isoform of interferon-tau to be administered to provide 5×10^8 Units, which Applicants have shown is effective to increase blood IL-10 level with no affect on interferon-gamma blood levels.

On a final note, and with respect to the Examiner's remark that human clinical trials would be necessary to practice the claimed method, Applicants trust that the remarks in the preceding paragraph illustrate that a human clinical trial is not needed to measure a protein's antiviral activity to determine the amount of protein needed to provide 5×10^8 Units/day.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

III. Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-6, 14, and 15 were rejected under 35 U.S.C. § 112, second paragraph for allegedly omitting essential steps. Specifically, the Examiner asserts that measuring IL-10 and interferon-gamma blood levels before and after initial administration of an interferon-tau is a critical step in practicing the method. Reconsideration is requested based on the following remarks.

The claimed method recites the feature that a dose of an interferon-tau of greater than 5×10^8 Units/day is administered. Applicants have established this dose of greater than 5×10^8 Units of an interferon-tau is effective to increase serum IL-10 levels (see, for example, Fig. 1D). There is, therefore, no need to measure the serum IL-10 levels before or after interferon-tau administration, since it is a technical fact that the recited dose will increase serum IL-10 levels. To practice the claimed method, one only need administer a dose of an interferon-tau of greater than 5×10^8 Units/day.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

IV. Double-Patenting Rejection

Claim 1-6, 14, and 15 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 7,083,782 (Liu et al.) in view of Soos et al. (*J. Immunol.*, 169:2231 (2002)).

The Examiner noted that a timely filed Terminal Disclaimer in compliance with 36 C.F.R. §1.321(c) would overcome an actual or provisional rejection on this ground. Enclosed herewith is an executed Terminal Disclaimer filed in accordance with C.F.R. §1.321(b) and (c) which disclaims the terminal portion of any patent issuing on the instant application that extends beyond the expiration of U.S. Patent No. 7,083,782.

The applicants submit that Terminal Disclaimer overcomes the rejection for obviousness-type double patenting and withdrawal of the rejection is respectfully requested.

V. Conclusion

Applicants believe that the present application is fully in condition for allowance. Early notice to this effect is earnestly requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 838-4402.

Respectfully submitted,
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